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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/730,329	12/04/2000	Varghese John	00228-US-NEW3	8197

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EXAMINER

KAM, CHIH MIN

ART UNIT PAPER NUMBER

1656

DATE MAILED: 12/07/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/730,329

Applicant(s)

JOHN ET AL.

Examiner

Chih-Min Kam

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 September 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 6-10, 13 and 14 is/are pending in the application.
- 4a) Of the above claim(s) 13 and 14 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 6, 8 and 9 is/are rejected.
- 7) ☒ Claim(s) 7 and 10 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>10/20/05</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of the Claims

1. Claims 6-10, 13 and 14 are pending.

Applicant's amendment filed September 27, 2005 is acknowledged, and applicants' response has been fully considered. Claims 6, 7 and 13 have been amended, and claims 1-5, 11, 12 and 15-21 have been cancelled. Claims 13 and 14 are non-elected invention and withdrawn from consideration. Therefore, claims 6-10 are examined.

Withdrawn Informalities

2. The previous objection to the specification is withdrawn in view of applicant's amendment to the specification, and applicant's response at pages 15-16 in the amendment filed September 27, 2005.

Withdrawn-Claim Rejections - 35 U.S.C. § 112

3. The previous rejection of claims 1-5 under 35 U.S.C. § 112, first paragraph, is withdrawn in view of applicant's cancellation of the claim in the amendment filed September 27, 2005.
4. The previous rejection of claims 1-10 under 35 U.S.C. § 112, second paragraph, is withdrawn in view of applicant's cancellation of the claim, applicant's amendment to the claim, and applicant's response at pages 16-17 in the amendment filed September 27, 2005.

Objection to New Matter Added to Specification

5. The substituted specification with deletion of brief description of the drawings, some sequences and brief description of sequence listing, filed June 21, 2004 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material

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which is not supported by the original disclosure is as follows: The substituted specification recites specific fragments of beta-secretase (e.g., residues 46-419, 46-452, and 63-423; paragraphs [0007]-[0009]) and full length of beta-secretase molecule (residues 1-501; paragraphs [0010]) but deletes the corresponding sequence identifier. The sequence listing filed June 21, 2004 do not contain the amino acid sequence of the full length of human beta-secretase, and its coding nucleotide sequence. Thus, the sequences for fragments or full length of beta-secretase cited in the substituted specification would have different scope from the sequences in the original specification, because the original sequences refer to specific fragments of human beta-secretase (i.e., SEQ ID NO:2), while the sequences cited in substituted specification do not refer to a specific reference sequence (i.e., SEQ ID NO:2).

Applicant is required to cancel the new matter in the reply to this Office Action.

Claim Objection

6. Claim 6 is objected to because of the misspelled word “cyclohexylmethyistatine”.

Appropriate correction is required.

New Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 6, 8 and 9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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8. Claims 6, 8 and 9 are indefinite because the claim indicates E is glutamine in SEQ ID NO:59, which is different from the sequence of SEQ ID NO:59 in the sequence listing that indicates E is glutamic acid. Furthermore, the “one letter code” for glutamic acid is E, and the code for glutamine is Q. The claims are also indefinite because of the use of the term “may optionally have”. The term cited renders the claim indefinite, it is not clear whether the phenyl group optionally has the substitution or not. Claims 8 and 9 are included in this rejection for being dependent on a rejected claim and not correcting the deficiency of the claim from which they depend.

Claim Objection

9. Claims 7 and 10 are objected to because the claim depends from a rejected claim.

Conclusion

10. Claims 6, 8 and 9 are rejected, and claims 7 and 10 are objected to.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (571) 272-0948. The examiner can normally be reached on 8.00-4:30, Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner’s supervisor, Kathleen Kerr can be reached at 571-272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

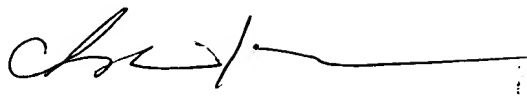
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Chih-Min Kam, Ph. D.

Patent Examiner



CHIH-MIN KAM
PATENT EXAMINER

CMK

December 2, 2005